

**REMARKS**

Claims 1-13 are pending in the application.

Claims 1-13 have been rejected.

Claims 4, 6, 8 and 11 have been amended, as set forth herein.

New Claim 14 has been added.

I. **REJECTION UNDER 35 U.S.C. § 112**

Claims 1-5 and 9-13 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The rejection is respectfully traversed.

The transitional phrase “having” has been, and is currently, commonly used in claim terminology, and the term is commonly known to be an open-ended phrase.

Claim 9 has been amended solely to correct the noted informality.

Claim 10 recites a functionality of the waisted region. The waisted region is an element/feature of the lead which is inserted in Claim 8. Accordingly, Applicant respectfully submits that the claim is definite.

Accordingly, the Applicant respectfully requests withdrawal of the § 112 rejection of Claims 1-5 and 9-13.

II. REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Yoon (US 5,484,426). Claims 1, 4, 6, 8 and 11 were rejected under 35 U.S.C. § 102(b) as being anticipated by Clark, et al. (EP 0 215 726). Claims 1-13 were rejected under 35 U.S.C. § 102(e) as being anticipated by King, et al. (US 6,161,047). Claims 1-13 were rejected under 35 U.S.C. § 102(e) as being anticipated by Errico, et al. (US 6,175,769). Claims 1-7 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kuzma, et al. (US 6,522,932). Claims 1-7 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kohnen, et al. (US 6,249,707). Claims 1, 4, 6, 8 and 10-12 were rejected under 35 U.S.C. § 102(e) as being anticipated Loeb (US 6,112,124). The rejections are respectfully traversed.

With respect to Yoon, Applicants' claimed invention includes elements/features other than and/or in addition to "a spinal stimulation device with a variable transverse dimension to mate with the spinal placement location." Neither Figure 14 or related text description discloses a lead having a plurality of terminals and a plurality of conductors. Yoon recites a tubular conductive trunk with solid conductive branches to provide a unipolar device. Col. 9, lines 1-21. A plurality of conductors is not disclosed. Figures 29 and 30 disclose a sponge material device. No electrodes, terminals or conductors are disclosed. Therefore, Yoon fails to anticipate each and every element/feature of the claimed invention. See, Applicant's Claims 1, 4, 6, 8 and 11.

With respect to Clark, Applicants' claimed invention includes elements/features other than and/or in addition to "an electrode array." Clark recites an electrode for the stimulation of the cochlea. Clark does not appear to disclose or mention "percutaneous" insertion or a "percutaneous insertion structure" or "percutaneously accessing." Moreover, Clark's electrode appears to be circular in shape, and does not have two principal surfaces arranged opposite to one another (opposing surfaces). See, Applicants' Claims 1, 4, 6, 8 and 11. Clark further fails to disclose a lead body wherein a greatest transverse dimension of the body of the lead is less than a corresponding interior dimension of the percutaneous introduction structure. See, Applicants' Claims 1, 6, 8 and 11.

With respect to King, Applicants' claimed invention includes elements/features other than and/or in addition to "a stimulation device." King's lead expands, and thus fails to provide a lead wherein the greatest transverse dimension of the body is less than a corresponding interior dimension of the percutaneous introduction structure. See, Applicants' Claims 1, 6, 8 and 11. Further, King fails to disclose that the lead body has a varying transverse dimension that enables flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides steerability of the lead. See, Applicants' Claim 4.

With respect to Errico, Applicants' claimed invention includes elements/features other than and/or in addition to "a spinal cord electrode assembly." Errico recites a paddle-type structure with an extending portion for suturing to the tissue. Errico does not appear to disclose or mention "percutaneous" insertion or a "percutaneous insertion structure" or "percutaneously

accessing.” Moreover, Errico discloses that “by techniques already known in the field of spinal surgery, the surgeon would place the electrode beneath the lamina . . .” (emphasis added). Col. 3, lines 41-44. As such, the foregoing teaching of Errico coupled with Errico’s Figures 1 and 2 (that illustrate an enormous paddle structure) provide sufficient evidence that Errico’s lead is not inserted percutaneously. Accordingly, Errico fails to disclose a lead body wherein a greatest transverse dimension of the body of the lead is less than a corresponding interior dimension of a percutaneous introduction structure. See, Applicants’ Claims 1, 6, 8 and 11. Further, Errico fails to disclose that the lead body has varying transverse dimension that enables flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides steerability of the lead. See, Applicants’ Claim 4.

With respect to Kuzma, Applicants’ claimed invention includes elements/features other than and/or in addition to “paddle-type electrode for spinal stimulation.” Kuzma’s lead expands, and thus fails to provide a lead wherein the greatest transverse dimension of the body is less than a corresponding interior dimension of the percutaneous introduction structure. See, Applicant’s Claims 1 and 6. Further, Kuzma fails to disclose that the lead body has varying transverse dimension that enables flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides steerability of the lead. See, Applicants’ Claim 4.

With respect to Kohnen, Applicants’ claimed invention includes elements/features other than and/or in addition to “paddle style lead.” Kohnen fails to disclose a lead with a varying

transverse dimension that enables flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides steerability of the lead. See, Applicants' Claim 4.

With respect to Loeb, Applicants' claimed invention includes elements/features other than and/or in addition to "an electrode array." Loeb recites an electrode array for the stimulation of the cochlea. Loeb does not appear to disclose or mention "percutaneous" insertion or a "percutaneous insertion structure" or "percutaneously accessing." See, Applicants' Claims 1, 4, 6, 8 and 11. Moreover, Loeb does not appear to have a waisted region as configured and disclosed in the Applicants' invention, and fails to disclose a lead body wherein a greatest transverse dimension of the body of the lead is less than a corresponding interior dimension of the percutaneous introduction structure. See, Claims 1, 6, 8 and 11. In addition, Loeb fails to disclose that the lead body has varying transverse dimension that enables flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides steerability of the lead. See, Applicants' Claim 4.

Accordingly, the Applicant respectfully requests the Examiner withdraw the § 102(b) and (e) rejections of Claims 1-13.

### III. NEW CLAIM 14

Applicant has added new Claim 14, and believes that it is patentable over the art of record.

IV. CONCLUSION

As a result of the foregoing, the Applicant asserts that the remaining Claims in the Application are in condition for allowance, and respectfully requests an early allowance of such Claims.

If any issues arise, or if the Examiner has any suggestions for expediting allowance of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at *rmccutcheon@davismunck.com*.

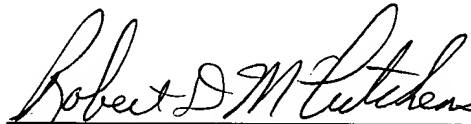
The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

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Date:

10/31/2003



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